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Medical Devices Step Out of Legal Metrology (Packaged Commodities) Shadow: 2025 Amendment Ends Labelling Confusion

AUTHOR Rahul Sundaram

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The Legal Metrology (Packaged Commodities) Amendment Rules, 2025 quietly unplugged every medical-device package from the empire of tape-measures, type-heights and width-to-height ratios that have governed ordinary consumer packs for the past fourteen years. The one-page notification brings to an end a regulatory tug-of-war that manufacturers, importers and even field inspectors had faced ever since the Medical Devices Rules, 2017 came into force under the Drugs and Cosmetics regime.

The Central Government acted under section 52(2)(j) and (q) of the Legal Metrology Act, 2009, the twin clauses that allow it to "exempt any package or class of packages" and to "make such provisions not inconsistent with the Act" as may be required in public interest. Using this enabling power, the Consumer Affairs Ministry did not create a brand-new set of obligations; instead, it simply said that wherever the 2017 CDSCO rules speak, the Legal Metrology rules will fall silent.

Rule 2(h) of the 2011 Packaged Commodities Rules is the definitional gateway: it tells inspectors what a "pre-packaged commodity" is. A fresh proviso now carves out "packages containing medical devices" and makes the Medical Devices Rules, 2017 the sole compass for every declaration that must appear on the label. The amendment is deliberately phrased in the continuous present tense "the provisions … shall apply" so that future changes made by CDSCO will automatically flow through without another metrology notification.

Rule 7(2) and 7(3) used to prescribe millimetre-precision for the height and width of every numeral and letter that spells out MRP, net quantity, customer-care number or the standard pack identifier. Medical-device labels no longer need to run that typographic obstacle course; the 2017 Rules, which focus on legibility and contrast rather than fixed measurements, will now decide what is acceptable.

Finally, Rule 33 has been re-numbered as sub-rule (1) and fortified with a new sub-rule (2). It bluntly states that "where the Medical Devices Rules, 2017 are applicable, the relaxation given under this rule shall not apply." In plain English, a manufacturer cannot seek a Legal-Metrology waiver for font size, language placement or dual-unit conversion if the device is already regulated by CDSCO. The gate for ad-hoc concessions has been shut; compliance must be sought within the medical-device regime.

The backdrop to these changes is a decade of jurisdictional overlap. Ever since the 2017 Rules introduced risk-based classification, plant registration, unique device identification and post-market surveillance, firms found themselves answering two masters: drug inspectors asking for clinical labelling and legal-metrology inspectors armed with steel rulers. Courts and fora across the country had begun to deliver conflicting orders some quashing seizure of stents because "drug rules prevail", others upholding fines for "non-compliant font height". The 2025 amendment removes that ambiguity at one stroke and places medical devices exclusively under the Central Drugs Standard Control Organisation.

For manufacturers, the operational impact is immediate: artwork cycles will shorten, dual-language stickers meant only to satisfy metrology can disappear, and import clearances should move faster. For consumers, nothing visible changes on the pack; the safeguards on safety, performance and traceability remain intact only the enforcing inspector now wears a different badge. For the regulatory architecture, the amendment is a classic example of "de-harmonisation through harmonisation": by exempting a sector from one law, the Centre has actually aligned it with another, more specialised one.

In a country that aspires to become a global med-tech hub, clarity is cheaper than compliance. The Legal Metrology Amendment Rules, 2025 deliver that clarity, proving that sometimes the most reformist thing a government can do is to simply step out of its own way. For further details write to contact@indialaw.in

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